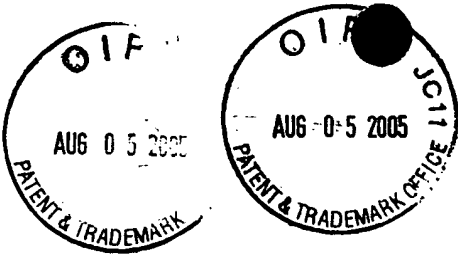


PCT

Docket No.: 2329-0107PUS1  
(PATENT)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

---

In re Patent Application of:  
Andres VALKNA et al.

Application No.: 10/528,073

Confirmation No.: @@@

Filed: March 17, 2005

Art Unit: N/A

---

For: OBTAINING AND USE OF THERAPEUTIC  
ANTIBODIES ENTERING INTO THE CELL

---

Examiner: Not Yet Assigned

**INFORMATION DISCLOSURE STATEMENT**  
**(SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL**  
**REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE**  
**1.114 RCE APPLICATION)**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

- ☒ a. Copies of cited U.S. patents and patent application publications are not included.  
Copies of foreign patent documents and non-patent literature are included.

☐ b. Some or all of the documents listed on the PTO-SB08 are not enclosed because they were cited in the International Search Report and copies should already be in the PTO file. If copies are needed, please contact the undersigned.

☐ c. REFERENCES PREVIOUSLY CITED OR SUBMITTED - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

@@@ filed @@@

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

☒ a. DOCUMENTS IN THE ENGLISH LANGUAGE - The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.

☐ b. DOCUMENTS NOT IN THE ENGLISH LANGUAGE - A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows:

☐ c. ENGLISH LANGUAGE SEARCH REPORT - An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).

☒ d. OTHER - The following additional information is provided for the Examiner's consideration. All of the cited references are discussed on pages 2 and 3 of the present specification.

IV. FEES (check one box)

☐ a. This Information Disclosure Statement is being filed concurrently with the filing of a new patent application; therefore, no fee is required.

☐ b. This Information Disclosure Statement is being filed concurrent with the filing of a continuation-in-part, continuation, or divisional patent application; therefore, no fee is required.

☐ c. This Information Disclosure Statement is being filed within three months of the filing date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required.  
(This section is not to be used with RCE's.)

☐ d. This Information Disclosure Statement is being filed within three months of the date of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required.

☐ e. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required.

☒ f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p).

☐ g. This Information Disclosure Statement is being filed before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)).

☐ No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached.

or

☐ See the statement below. No fee is required.

V. STATEMENT UNDER 37 C.F.R. § 1.97(e)

(check only one box)

The undersigned hereby states that:

☐ a. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than 30 days prior to the filing of this IDS; or

☐ b. Each item of information contained in the IDS was first cited in any communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or

☐ c. No item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of IDS was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.

☐ d. Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned states that each item of information contained in the IDS was first cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby states that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application and, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

VI. PAYMENT OF FEES (check one box)

- ☐ The required fee is listed on the attached Fee Transmittal.
- ☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated: AUG 5 2005

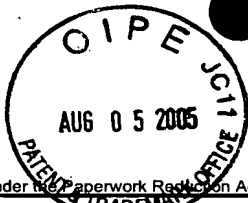
Respectfully submitted,

By 

Marc S. Weiner  
Registration No.: 32,181  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Rd  
Suite 100 East  
P.O. Box 747  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant

Attachment(s):

- ☒ PTO-SB08  
☒ Documents  
☐ Foreign Search Report  
☐ Fee  
☐ Other:



PTO/SB/08B (08-03)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)	<b>Application Number</b>				
	<b>Filing Date</b>				
	<b>First Named Inventor</b>	Andres VALKNA			
	<b>Art Unit</b>				
	<b>Examiner Name</b>				
<b>Sheet</b>		<b>of</b>		<b>Attorney Docket Number</b>	

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	1	DAHMANE et al., "Activation of the transcription factor Gli 1 and the Sonic hedgehog signalling pathway in skin tumours", Nature, Oct. 1997, pages 876-81, Vol. 389, 6653, Nature Publishing Group, London	
	2	KOGERMAN et al., "Mammalian suppressor-of-fused modulates nuclear-cytoplasmic shuttling of Gli-1", Nature Cell Biology, Sept. 1999, pages 312-9, Vol. 1, 5, Nature Publishing Group, London	
	3	LECERF et al., "Human single-chain Fv intrabodies counteract in situ huntingtin aggregation in cellular models of Huntington's disease", Proceedings of National Academy of Sciences USA, April, 2001, pages 4764-9, Vol. 98, 8, National Academy of Sciences, Washington, DC	
	4	POOGA et al., "Cell penetrating PNA constructs regulate galanin receptor levels and modify pain transmission in vivo", Nature Biotechnology, Sept. 1998, pages 857-61, Vol. 16, 9, Nature Publishing Group, London	
	5	RIDDER et al., "Generation of rabbit monoclonal antibody fragments from a combinatorial phage display library and their production in the yeast Pichia pastoris", Bio/technology, March 1995, pages 255-60, Vol. 13, 3, Nature Publishing Company, New York	
	6	SCHWARZE et al., "In vivo protein transduction: delivery of a biologically active protein into the mouse", Science, Sept. 1999, pages 1569-72, Vol. 285, 5433, American Association for the Advancement of Science	
	7	STEINBERGER et al., "Functional deletion of the CCR5 receptor by intracellular immunization produces cells that are refractory to CCR5-dependent HIV-1 infection and cell fusion", Proceedings of National Academy of Sciences USA, Jan. 2000, pages 805-10, Vol. 97, 2, National Academy of Sciences	
	8	STRUBE et al., "Characterization of anti-cyclin E single-chain Fv antibodies and intrabodies in breast cancer cells: enhanced intracellular stability of novel sFv-Fc intrabodies", Journal of Immunological Methods, May 2002, pages 149-67, Vol. 263, 1-2, Elsevier B.V	

<b>Examiner Signature</b>		<b>Date Considered</b>	
-------------------------------	--	----------------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.